UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE)
LITIGATION) MDL No. 1456
) Master Case No. 01-12257-PBS
)
THIS DOCUMENT RELATES TO:) Subcategory Case No. 06-11337-PBS
)
United States of America ex rel. Ven-a-) Hon. Patti B. Saris
Care of the Florida Keys, Inc., et al. v. Dey,)
Inc., et al., Civil Action No. 05-11084-PBS)

MEMORANDUM OF UNITED STATES IN OPPOSITION TO DEY DEFENDANTS' MOTION IN LIMINE TO EXCLUDE OPINIONS OF MARK DUGGAN, PH.D

INTRODUCTION

This Court has had the benefit of detailed inquiry into the damages methodology and calculations of the plaintiffs' expert, Mark G. Duggan, Ph.D, in connection with the *Daubert* motion filed by Abbott Laboratories in this MDL. The briefing in that case, and the testimony given therein, show that Dr. Duggan's damages model and the calculations he performed were based on reliable and voluminous data, and sound and testable econometric principles. In the instant case against Dey, Dr. Duggan has performed similar damages calculations using similar data and principles, except that he has not performed any extrapolation in connection with the Medicare damages.¹

¹ Dr. Duggan's work is generally described in the following documents:

^{1.} Duggan Expert Report ("Duggan Expert Rep.") (Exhibit 1 to Declaration of Marisa A. Lorenzo ("Lorenzo") (Master Doc. #6992-1, Sub. #732-1);

^{2.} Duggan Rebuttal Report ("Duggan Rebutt. Rep.") (Attachment A to (continued...)

Dey's attack mostly consists of challenges to legal rulings of this Court on the meaning of WAC and AWP; it fails to reveal any deficiency in Dr. Duggan's opinions and analyses. Accordingly, the Court should deny Dey's motion.

I. DR. DUGGAN'S DAMAGES CALCULATIONS ARE THE PRODUCT OF RELIABLE PRINCIPLES AND METHODS

A. Dr. Duggan's Methodology

Dey paints an inaccurate and misleading picture of Dr. Duggan's methodology for selecting alternative WACs and AWPs. Dey incorrectly suggests that Dr. Duggan recalculated Dey's WAC and simply marked it up by 25 percent to determine an alternative AWP. Dey Mem. 3-4. This is not the case. As Dr. Duggan explains in his expert report, he did not just "mark up" Dey's WAC to calculate an alternative AWP; rather, he utilized Dey's transaction data to calculate alternative AWPs as 125% of the average price to the pharmacy class of trade:

I replace the AWP with 125 percent of the average pharmacy-specific price in Dey's indirect transaction data to

¹(...continued)

Declaration of Mark G. Duggan, Ph.D In Support of Motion to Exclude Certain Testimony of W. David Bradford, Ph.D ("Duggan Decl.") (U.S. Ex. 1 hereto);

^{3.} Duggan Supplemental Report ("Duggan Suppl. Rep.") (Attachment B to Duggan Decl. (U.S. Ex. 1 hereto));

^{4.} February 5, 2010, Letter of Mark Duggan (Lorenzo Ex. 21);

^{5.} July 23, 2009, Declaration of Mark Duggan, Henderson Common Summary Judgment Ex. 41 (Master Doc. #6310-53&54, Sub. #308-53&54);

^{6.} September 21, 2009, Declaration of Mark Duggan, Ph.D., Henderson Summary Judgement Reply Ex. 90 (Master Doc. #6528-90, Sub. #468-90); and

^{7.} Deposition testimony of which Dev has only attached limited excerpts.

determine how spending by Medicaid programs that used the AWP and by the Medicare program would have changed if alternative prices had been used. This alternative AWP will overstate the actual average price paid by pharmacies on transactions made through wholesalers by 25 percent. Additionally, because pharmacies tend to pay a higher price than do other customers for the same product, this scaled price will on average be greater than a similarly scaled average price for all indirect customers, thus leading to a lower discrepancy than if I were to consider all customers. For those states that use the WAC, I replace it with the actual average price paid by pharmacies to wholesalers in Dey's indirect data, as this is a more conservative approach than using the average actual wholesaler price from Dey's direct data.

Lorenzo Ex. 1 (Duggan Report) at p. 10. Dey's mischaracterization of Dr. Duggan's methodology should be disregarded.

B. Dr. Duggan's Alternative WAC Is a Proper Basis For Estimating Medicaid Damages Relating to WAC States

Dey argues that Dr. Duggan's alternative WAC is unfounded because WAC is not an average price but is an undiscounted price. This issue has already been decided adversely to Dey in *Massachusetts v. Mylan Laboratories*, 608 F. Supp. 2d 127, 143 (D. Mass. 2008) ("Combining all of the terms, 'wholesale acquisition cost' plainly means 'the price paid to acquire goods in quantity for resale.' It does not mean a list price; it means the amount that goods actually cost.").

Dey cites to a definition of WAC that was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173, codified at 42 U.S.C. § 1395w-3a(c)(6)(B). This definition was created for a very

specific use in the Medicare program, where it may be used as a basis for payment only in three very limited situations: (1) for single-source drugs, payment at WAC+6% may be made when the weighted average WAC for the applicable HCPCS code is lower than the weighted average ASP, *id.* § 1395w-3a(b)(1)(B), (b)(4); (2) the Secretary is authorized to use WAC to determine the payment amount for the first quarter of a drug's sales, when there is no history of actual sales prices, *id.* § 1395w-3a(c)(4); and (3) in the event of a public health emergency WAC may be used where "there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters," and then only until the price and availability of the drug has stabilized and is reflected in the manufacturer's ASP. 42 U.S.C. § 1395w-3a(e). There is no hint of congressional intent to create a loophole in Medicaid's use of "estimated acquisition cost" as the foundation of pharmacy reimbursement.

C. Dr. Duggan's Testimony Regarding Alternative AWPs Is Admissible

Dey first argues that Dr. Duggan's use of a 25% scaling factor is unsupported and therefore inadmissible. Dey incorrectly characterizes the 25% factor as something borrowed from Dr. Duggan's analysis in the *Abbott* case without the benefit of any economic analysis. But Dr. Duggan's testimony indicates that his scaling factor was in significant part a reflection of the discounts off AWP used by state Medicaid programs and the federal Medicare program. *See* Duggan Dep., 2/26/2009, at 121:6 - 121:19

(Lorenzo Ex. 7) (explaining that the 125 percent mark up "was selected with an eye to . . . this issue of the Medicaid pharmacy AWP discounts). Dr. Duggan elaborated in his deposition taken by the Roxane defendants:

At some level the most natural price at first blush without sort of drilling down and thinking about the complexities, would be the actual average price. . . . However, in the interests of being conservative, recognizing that many states employ formulas that reimburse AWP minus 5 percent, AWP minus 10 percent, and so forth, this 25 percent cushion, this 25 percent markup over the actual average price had resulted in the ingredient cost being in virtually every case -- the ingredient cost reimbursement in virtually every case greater than the actual average price. So that was sort of one of the factors that I considered.

Duggan Dep. 3/6/2009, at 253:9 - 254:16 (U.S. Ex. 2 hereto). There is nothing arbitrary or irrational about using a conservative adjustment factor to account for discounts used by the Medicare and Medicaid programs. Nor is it impermissible for Dr. Duggan to have considered a customary markup by price-reporting services of 20 to 25 percent over WAC. *See* Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris (MDL Doc. #1384) at pp. 15-17; *see also Pension Comm. of the Univ. of Montreal Pension Plan v. Banc of Am. Secs*, – F. Supp. 2d –, 2010 WL 648369, *14-15 (S.D.N.Y. Feb. 22, 2010) ("In light of this evidence, Collins's uncertainty as to whether the twenty percent discount was 'overall industry practice,' does not render his methodology unreliable."). An analogous 30 percent "speed limit" has been upheld in related AWP litigation. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir.

2009). Moreover, the 25 percent adjustment only serves to reduce the damages that would otherwise be calculated, and thus Dey cannot claim any prejudice.

Dey argues that Dr. Duggan's method for determining alternative AWPs is inconsistent with his earlier article, "The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing." Dey Mem. 8-9. To the contrary, in that paper Dr. Duggan and co-author Fiona Scott-Morton found that Medicaid's average AWP-based reimbursement amounts per prescription were a reliable guide to actual average prices. *See* Lorenzo Ex. 9 at 11-12 n.17 ("It therefore appears that our Medicaid data provide a good estimate of average pharmaceutical prices for all health care consumers in the United States."). In any event, that paper did not purport to draw conclusions about the terms "average wholesale price" or "estimated acquisition cost" as used in Medicare or Medicaid reimbursement laws, nor did the paper comment on the truthfulness of any manufacturer's price reporting conduct.

D. Dr. Duggan Did Not Inappropriately Ignore Wholesaler Data

Dey's claim that Dr. Duggan's testimony must be precluded because he did not use wholesaler transaction data ignores that Dr. Duggan's objective was to determine alternative AWPs that *Dey* could have reported, and then calculate what the Medicaid and Medicare programs would have paid had they used those more accurate prices. Dey did not have access to the wholesaler data for purposes of reporting prices, and neither

Medicare nor Medicaid had such data for purposes of determining reimbursement.²

Dey's argument essentially asks the Court and the trier of fact to try to imagine what might have happened had Dey, as well as Medicare and Medicaid, had access to and used different sources of data never available to them during the relevant time period. Dr. Duggan did not err in failing to engage in such speculation.

In any event, Dey's selective quote from a deposition of Dr. Duggan is misleading. Dey Mem. 10-11. As Dr. Duggan explained in his Rebuttal Report, the alternative AWPs he calculated were on average *higher* than the Cardinal prices, meaning that if he "had used Cardinal's average prices" in place of his alternative AWPs, "the total damages to the federal government would have been higher." Duggan Decl. (Ex. 1 hereto), Attachment A (Rebuttal Report), at 11-12 (explaining, by way of example only, that Dr. Duggan's calculated AWP for Dey's Albuterol Sulfate product, which accounted for more Medicaid sales than any other Complaint product, was \$7.77, compared to the Cardinal price of \$6.55).

II. THERE IS NO MERIT TO DEY'S CONTENTION THAT DR. DUGGAN'S METHODOLOGY IS BASED ON UNFOUNDED ASSUMPTIONS

Dey argues that Dr. Duggan improperly assumes that average sales prices net of discounts could have been reported and published for use by the Medicare and Medicaid programs. Dey reasons that the Medicaid Rebate Agreement between Dey and the

² See Memorandum in Support of United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D (Master Doc. #6914, Sub. #693) ("U.S. Bradford Mem.") at 17-18.

Secretary affords confidential protection to such numbers, and therefore such numbers never could have been published. Dey Mem. 11-12. This is a slightly different twist to Dey's argument, made in its motion to dismiss, that its Medicaid Rebate Agreement precludes the government's claims. This Court, of course, already has rejected that argument. *United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Dey, Inc.*, 498 F. Supp. 2d 389, 401 (D. Mass. 2007). Dr. Duggan's methodology, which includes a 25 percent scaling factor over the actual average price to the retail pharmacy class of trade, does not assume that Dey was required to report for publication its AMPs. It does assume that Dey's Medicaid Rebate Agreement is not a license to report knowingly false prices, and that Dey could have reported for publication prices within 125 percent of its actual average price to the retail pharmacy class of trade if it chose.

Dey further argues that Dr. Duggan wrongly assumes that state Medicaid agencies and the Medicare DMERCs would have used his alternative AWPs if they had been published. Dey Mem. 12-13. This is simply a re-hash of "government knowledge" arguments made in summary judgment proceedings. By law, the Medicare program

³ See Dey Defendants' Memorandum of Law In Support of Their Motion To Dismiss the United States' Complaint (Dkt #3508-1) at 21-23.

⁴ The confidentiality language of the Rebate Agreement, which is based upon the confidentiality provisions of the Rebate Statute, 42 U.S.C. § 1396r-8(b)(3)(D), is for the benefit of the manufacturer and does not prohibit the manufacturer from disclosing such information if it so chooses. Thus, the Agreement provides that AMP data submitted by the manufacturer "is confidential and shall not be disclosed *by the Secretary or a State agency* in a form which reveals the Manufacturer, or prices charged by the Manufacturer" Lorenzo Ex. 2 at 9 (emphasis added). Had Dey decided that reporting its AMPs was the most convenient way to report truthful prices to the compendia, Dey could have reported those prices.

relied on AWPs, and it is reasonable – indeed necessary – for Dr. Duggan to assume that Medicare would have used alternative truthful AWPs had Dey reported them for publication. *See generally Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d at 133 ("Upon submission of a claim, the computer system automatically applies the claims processing algorithm, based on the applicable regulation, determining and paying out the lowest of" pricing component). Dey's quotation from deposition testimony of CMS official Deidre Duzor (Dey Mem. 13) is unhelpful because she was not asked, and did not testify, about what Medicare would have done had the *Red Book* published the alternative Dey AWPs that Dr. Duggan used in his analysis, or alternatively, had all manufacturers reported in accordance with Dr. Duggan's methodology.

Dey also argues that Dr. Duggan is wrong to assume that dispensing fees would have remained unchanged if Dey had reported Dr. Duggan's alternative prices (or alternatively if all manufacturers had reported prices according to Dr. Duggan's methodology). Dr. Duggan addresses this argument in his Rebuttal Report, both with respect to Medicaid dispensing fees (Rebuttal Report at 5-7), and Medicare dispensing fees (Rebuttal Report at 13-16). As Dr. Duggan demonstrates, it is inappropriate to speculate regarding the secondary effects, if any, of reductions in the reported AWPs of Dey's drugs or drugs of other manufacturers. Dr. Duggan has properly demonstrated and quantified the direct effects of Dey's false price reporting conduct. Even assuming evidence about secondary or tertiary effects is admissible in this case, which plaintiffs

dispute, the burden of proving and quantifying such effects lies with Dey, not with the United States or its expert. The speculative nature of such an exercise is also demonstrated in the Reply Memorandum of United States in Support of Motion to Exclude Certain Opinions of W. David Bradford, Ph.D (Master Doc. #7055-1, Sub. #752-1) at pp. 4-14, 16-17.

III. THERE IS NO MERIT TO DEY'S CONTENTION THAT DR. DUGGAN USED UNRELIABLE EXTRAPOLATIONS

A. Dr. Duggan's Medicaid Extrapolations Are Sound

The Medicaid extrapolation calculations of Dr. Duggan are based on his thorough examination of the entire universe of data in the context of the applicable reimbursement methodologies, together with the use of an extremely large sample from 14 states encompassing almost 11 million claims and over \$400 million in payments, representing nearly two-thirds of the entire universe. Lorenzo Ex. 1at Table 27; see also 7/23/2009 Declaration of Mark Duggan, Henderson Common Ex. 41(Master Doc. #6310-53, Sub. #308-53), and 9/21/2009 Declaration of Mark Duggan, Ph.D., Henderson Reply Ex. 90 (Master Doc. #6528-91, Sub. #468-91). The inherent precision of this enormous sample was further verified by Dr. Duggan through the "out-of-sample" re-adjudication of another \$78 million in claims for 16 more states, see Lorenzo Ex. 20 at Table A, and through the use of confidence intervals computed using appropriate econometric principles. Lorenzo Ex. 21. In contrast, Dey's motion is based on little more than unsupported argument.

For example, Dey's criticism based on the non-random selection process is not only unsupported by citation to any authority, it ignores that non-random samples are used routinely. *See, e.g., Manual on Scientific Evidence*, p. 244 (nonprobability samples are often used and found to be reliable); *and see* U.S. Memorandum in Opposition to Abbott Daubert Motion (Master Doc. #6600, Sub. #500) at 15. Similarly, Dey's skeletal arguments resting on the number of states in the sample are conclusory, and unsupported by any actual statistical or mathematical analysis. A meritorious *Daubert* challenge must be based upon more than unsupported claims that a sample should have been larger, especially in this case where so much actual econometric work has been performed which supports the sample.

In large part, Dey demands a standard of perfection that is simply not applicable. An expert opinion is not excludable on a *Daubert* challenge even if it is wrong, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993) ("The proponent need not prove to the judge that the testimony is correct"), and certainly not because it supposedly contains some modest error which simply goes to the weight of the evidence and can be decided by the jury. *In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d 20, 86 (D. Mass. 2007). Moreover, the failure to include all possible factors in a reasonable estimation of damages is not fatal. *Id.*; *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 732 (N.D. Ill. 2007) (expert admissible even where data was missing and

expert may have failed to account for all variables; the conclusions were based on articulable standards and on the expert's experience, not speculation) (citations omitted).

Dey argues that Dr. Duggan's analysis of the claims data of an additional 16 states demonstrates an unacceptable rate of error. Dey Mem. 18. For 15 of those states (those for which Dr. Duggan originally had state-produced claims data), Dr. Duggan's claim-by-claim results varied from the extrapolation results by less than 5.7 percent. Dey Ex. 20. When Dr. Duggan included Alabama, whose claims data was not originally available to Dr. Duggan but was produced by Dey, the variance increases to 10.19 percent; however, Dr. Duggan explains that Alabama, which is a WAC state, is not representative of the remaining states (all but one of which are AWP states), because Dey's WACs are much closer to Dey's true transaction prices than are its AWPs. *Id*.⁵ Dey's non-systematic, non-mathematical fixation on "outliers" to the exclusion of the remainder of the universe provides no basis upon which to draw any conclusions useful to a *Daubert* inquiry.⁶

⁵ Dey also continues Abbott's misleading efforts to suggest that Dr. Duggan had no data for the extrapolated states. However, it is undisputed that Dr. Duggan possessed and utilized reliable data for *every* state and time period for which he calculated damages. Dr. Duggan used \$400 million in utilization data which had been obtained directly from the 14 states, and \$200 million that had been obtained directly from the states by CMS in the form of State Medicaid Research Files (SMRF), known most recently as the Medicaid Analytic Extract (MAX), and the State Drug Utilization Data (SDUD).

⁶ Dey's approach also echoes Abbott's illogical position that the variability of the sample prevented a reliable extrapolation to the remainder of the universe, while concurrently using the variable results of the additional state-by-state analysis as proof that the extrapolation is (continued...)

Moreover, the accuracy of the extrapolation has been confirmed not just by Dr. Duggan, but also by Dey's expert. Dr. Duggan's confidence interval calculations demonstrated a high level of certainty that the results are accurate, to within 7 to 8 percent of his calculated amount. Lorenzo Ex. 21. The results of the comparable analysis performed by Dey's expert are not dramatically different; the 16-state claim-by-claim re-adjudication by Dey's expert was within about 20 percent of the amount estimated from Dr. Duggan's extrapolation methodology, *see* Lorenzo Ex. 20, Table A (referring to Bradford Figure 42), and the confidence intervals as "corrected" by Dey's expert resulted in 95 percent certainty that the extrapolation is accurate to within 17 percent. Lorenzo Ex. 22. A successful *Daubert* challenge cannot be based upon quibbling over whether the error rate is in the range of 7 to 10 percent as compared to 17 to 20 percent. That is a classic jury issue.

Dey's criticism of Dr. Duggan's damages estimates for earlier periods of the same state (the "within-state" extrapolations) are also unsupported and incorrect. Dey claims that Dr. Duggan conducted no analysis of the reimbursement changes of particular states

⁶(...continued) unreliable. The logical conclusion is the opposite. The variable results of the extra state-by-state analysis mirrors the variability of the states in the sample, exactly what would be expected in a valid sample. In any event, a proper challenge on this issue needs to be rooted in econometric analysis, not rhetoric.

⁷ Specifically, the confidence interval showed the results as 90 percent certain to be accurate to within 6.96 percent and 95 percent certain to be accurate to within 8.27 percent.

 $^{^{8}\,}$ Dr. Duggan disagrees with Dr. Bradford's criticisms in his March 17, 2010, letter, and reserves the right to respond at the time of trial.

over time. Dev is absolutely incorrect. Dr. Duggan was well aware of the manner in which the state methodologies changed over time; he directly examined the impact of any such changes through his review of the data; he adjusted his calculations downward to account for differences; and he verified the accuracy of his results. See, e.g., Lorenzo Ex. 1 (Duggan Report), pp. 38 to 40; Henderson Common Ex. 41, ¶¶ 77 - 82; U.S. Ex. 1 hereto, Attachment A (Rebuttal Report) at 16 - 18. For example, if Dr. Duggan obtained data directly from a state for 1995 forward, but calculated damages for earlier periods, he reviewed the actual SMRF/MAX and SDUD claims data and the state reimbursement method for the earlier periods. He also examined the spread for the earlier periods by comparing the published prices to the actual average prices. If the spread was lower in earlier years, he adjusted his damage calculations downward in a proportionate amount, but never upwards if the spread was larger in earlier years. U.S. Ex. 1, Attachment A (Rebuttal Report) at 17 - 18. He checked on the accuracy of this method by pretending that his state-produced data started a year later. *Id*. In sum, Dev's accusation that Duggan conducted no analysis of this issue is wrong, and Dey has failed to demonstrate any supposed inaccuracy resulting therefrom.

B. Dr. Duggan Did Not Perform Extrapolations In His Medicare Calculations

Contrary to Dey's assertion, Dr. Duggan did not extrapolate when he calculated Medicare damages.⁹ Rather, in the few instances where there were missing arrays (for ipratropium bromide, nine quarters out of 120), he assumed that the allowable amount was based on the pricing shown in either the preceding or subsequent adjacent array, whichever resulted in the least damages calculated for the quarter. Rebuttal Report p. 21. If anything, this approach has resulted in an understatement of damages. *Id.* The correctness of Dr. Duggan's assumption will be demonstrated at trial, through the testimony of fact witnesses. For example, Robin Stone, the pricing analyst for Palmetto GBA (DMERC Region C), prepared a summary in which she identified the operative arrays for ipratropium bromide. See Deposition of Robin Stone (U.S. Ex. 3 hereto) 21:1 -21:10, 473:13 - 475:10, and accompanying Exhibit Abbott 522. Regarding two missing arrays for 1999 Q1 and Q2, Ms. Stone's summary exhibit states, in the "Comment" column, "Based on E:\nonPrivDATA\Item 1 Drug Files (Pricing information)\2001 DMERC Drugs\95 thru Current Qtrly Updates.zip, it is most likely QTR1 & QTR2 1999 arrays are the same as either QTR4 1998 or QTR3 1999 since the fees remained the same." Thus, it is evident that Ms. Stone reviewed relevant electronic files and

⁹ Dey's reference to the government's withdrawal of certain of its Medicare damages claims in the *Abbott* case (Dey Mem. at fn. 7) is misleading and irrelevant. In that case, the government withdrew damages derived from 70 non-DME Part B carriers; the government did *not* withdraw any of the DME-related damages.

concluded that the array governing these two quarters was the same as either the immediately preceding array (1998 Q4) or the next subsequent array (1999 Q3). This is totally consistent with the approach taken by Dr. Duggan. Evidence will show that there were no new products or price changes published in the Red Book during each relevant period that would have given rise to some different array.

Dey argues that "Dr. Duggan does not have an array for DMERC A until 1999
Q3, yet he calculates over \$7 million of damages for the nine previous quarters." Dey
Mem. 20. However, the DMERC A pricing analyst, Colleen King (whom the
government expects to call as a witness at trial), has identified the operative array for this
time period. Specifically, she has stated in a sworn declaration that, based on her detailed
review of DMERC A pricing files, she received an array (bates-stamped AWQ057-0677)
from AdminaStar Federal (another DMERC) in April 1997, and she "adopted this pricing
for K0518 [the applicable HCPCS code for ipratropium bromide] beginning April 1,
1997." Her declaration further states that "the array at AWQ057-0677 remained
operative for DMERC A for the KO and KP modifiers until the third or fourth quarter of
1999." Declaration of Colleen King, February 2, 2009 (U.S. Ex. 4 hereto) at ¶ 20.

The evidence at trial will support Dr. Duggan's methodology. Dey's arguments regarding Dr. Duggan's Medicare calculations are therefore meritless and should be rejected.

CONCLUSION

By:

For the foregoing reasons, the Court should deny Dey's motion to exclude opinions of Dr. Duggan.

Respectfully submitted,

TONY WEST ASSISTANT ATTORNEY GENERAL

UNITED STATES ATTORNEY

CARMEN M. ORTIZ

/s/ Laurie A. Oberembt

Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

/s/ George B. Henderson, II
George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

FOR THE RELATOR,

James J. Breen The Breen Law Firm, P.A. 5755 Northpoint Parkway, Suite 260 Alpharetta, GA 30022 Tel. (770) 740-0008 Gary Azorsky, Esq. Susan Schneider Thomas, Esq. Berger & Montague, P.C. 1622 Locust St. Philadelphia, PA 19103 (215) 875-3090

Dated: April 21, 2010

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
George B. Henderson, II
Assistant U.S. Attorney

Dated: April 21, 2010